LifeWave BST User Manual

LifeWave
Hi-Tech Medical Devices

BST
Bioelectrical Signal Therapy™

For Hospital, Clinic and Home Care

www.life-wave.com

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Introduction

LifeWave BST-Bioelectrical Signal Therapy™ a proprietary (to Live-Wave) device indicated for the treatment of chronic ulcers. The device emits a specific electrical signal across the wound to stimulate the natural wound healing process of the human body. This signal was identified on humans during the healing process of acute healing wounds and found to be associated with the nerves action during the healing process. The transmission of this signal to non healing chronic wound imitates and creates the electrical field of the "normal" wound healing process. The BST signal is applied to the wound by a single channel Bioelectrical generator to a pair of surface electrodes ("BST electrodes") that are attached to the healthy skin around the wound. The use of each pair of electrodes is according to the duration marked on the electrodes package. LifeWave BST is a user-friendly, easy to operate medical device.

Indications for Use

LifeWave BST is indicated for the treatment of chronic ulcers **i.e,** hard-to-heal wounds.

General Device Description

LifeWave BST is comprised of the following components:

1. **BST device (Bioelectrical generator):** a computerized system based on specially designed software which generates the treatment signal.

2. **LifeWave BST electrodes**: Pair of disposable electrodes that deliver (Bioelectrical current) to the skin surrounding the wound. The duration of usage of the electrodes is indicated on the electrode's labels.

Contraindications

Do not use LifeWave BST if:

- You are below 18 years old.
- You have an active pacemaker or defibrillator or any other implanted electrical device.
- You are pregnant or nursing.
- You have wounds on the chest or epigastric region **i.e,** middle or upper abdomen.
- You are being treated with metal ion-containing wound-care products, such as silver dressings.
- There is presence of a malignancy (cancer) less than 10 cm distance from your wound.
- You were diagnosed with Epilepsy or suffer from other neuroexcitatory conditions (related to the nervous system).
- If there is presence of over-granulation (rough) tissue, discontinue treatment immediately.
- Do not use LifeWave BST on metal implant in direct proximity to the wound.

Side Effects

In addition to LifeWave BST's therapeutic effect, some side effects may occur during treatment, such as light itching, tingling, redness or discomfort in areas where the electrodes were placed. If these side effects bother you and persist for more than a few days, or even if the side effects cease spontaneously or with local treatment, please contact your physician.

Some side effects requiring medical attention may include signs of allergic reaction, such as a skin rash, severe itching, skin blisters, swelling, or consistant redness. If any of these reactions or side effects occur, please contact your physician immediately.

Warnings

- Avoid cellular phones or any communications equipment when operating LifeWave BST.
- Do not operate LifeWave BST near shortwave or microwave therapy equipment.
- Do not simultaneously connect LifeWave BST and any other high-frequency equipment to yourself.
- Do not open the BST device; an electrical shock hazard exists.
- Do not use LifeWave BST if there are any visible signs of damage to the connector cable, electrodes or the BST device.
- Do not expose LifeWave BST to water.
- You cannot use another manufacturer's cables or electrodes.
- Do not apply LifeWave BST electrodes directly on the wound itself or to its boundaries, see Paragraph "Electrode connection".
- Do not attach LifeWave BST electrodes to each other.
- Do not fold or bend the LifeWave BST electrodes.
- Carefully position all cables so you do not become entangled in them.
- Ensure that you do not lie down or sit on any LifeWave BST components during treatment.
- Operate LifeWave BST according to the conditions specified in the EMC Parameters section of this manual.
- Do not sterilize any part of the LifeWave BST electrodes, LifeWave BST connector cable or BST device; damage or destruction may result.
- Refer all service calls to your physician or distributor.

Precautions

- LifeWave BST Electrodes are disposable and intended for a single wound. Each wound requires a new pair of electrodes.

- Inspect the wound frequently following the procedure recommended by your physician. Contact your physician if deterioration occurs or if you suspect a worsening of the wound condition. If the wound seems to be worsening or changes colors including black, yellow or green, stop using the LifeWave BST and consult your physician.

- If the wound is infected, treat the wound according to your physician's instructions.

- If you have an excessive growth of scar tissue, or if you are prone to form excessive growth of scar tissue at the wound area, consult your physician before using the device.

- If you have advanced heart (cardiac) disease, uncontrolled bleeding disorders, or if you have a metallic implant, consult your physician before using the device.

- In case of a malignancy (cancer), any signs of deterioration occurring faster than expected should be followed up with your physician.

- Ensure that the BST device and connector cables underwent a cleaning and disinfection process as described in the cleaning and disinfection section before transferring them from one wound to another, if applicable.

- LifeWave BST needs to be operated according to the EMC parameters listed in Tables 1, 2, 4, and 6 at the end of this manual.

Before You Begin

Please read the user manual before using LifeWave BST.

Fig. 1. BST device

Fig. 2. Power cable

Fig. 3. Connector cable

Fig. 4. LifeWave BST disposable electrodes and their lead

Fig. 5. Power switch

Fig. 6. Display contrast knob

Fig. 7.Connection of the connector cable to the BST device

Fig. 8. Connection of the electrode's connector to the connector cable

Contents

Each LifeWave BST package contains the following:

1. **BST Device (Fig. 1)**
2. **Power Cable (Fig. 2)**
3. **Connector Cable (Fig. 3)**
4. **LifeWave BST disposable Electrodes and their lead (Fig. 4)**

Please check that you have all the components before starting treatment.

Power Connection

1. Place the BST device (Fig. 1) on a clean flat surface and connect the power cable (Fig. 2) to the BST device.
2. Plug the power cable (Fig. 2) into a wall socket and turn on the BST device using the power switch (Fig. 5) .
3. The LifeWave BST logo appears on-screen, indicating that the system is ready.

Note:
To adjust the display contrast, turn the knob (Fig. 6) located on the right side of the BST device.

If the timer from a previous treatment is displayed, switch the power switch (Fig. 5) off and turn on again to reset.

Electrode Connections

Clean and dry the skin around the wound according to your physician's instructions. Cleaning is necessary to ensure that the skin is free of any dirt or ointments and that it is dry enough to enable the attachment of the electrodes.

1. Connect the connector cable (Fig. 3) to the BST device (Fig. 7).
2. Open the electrodes packet.
3. Separate and remove the outer lining from the electrodes to expose the electrode's sticky surface, and try not to touch the sticky surface.
4. Place the electrodes firmly on the healthy skin on opposite sides of the wound. Each electrode's concave edge should be 1.5– 2 cm away from the edge of the wound.
5. Connect the electrode's connector to the connector cable (Fig. 8).

Treatment Session

The duration of the programmed treatment session is 30 minutes, two to three sessions per day per wound. Your physician may instruct you to perform additional sessions per wound. Each session should be no more than 30 minutes, with a minimum of 5 hours between sessions, on the same wound.
Important Note: For achieving best results it is important to follow the treatment regimen as instructed by your physician.

Start Treatment

Ensure that the electrodes are firmly attached to the surrounding skin throughout treatment.

BST operating buttons

1. Press the green START button (left button).

2. Two check marks (✓✓) will be displayed indicating that the LifeWave BST is properly connected and ready for use.

✓✓ on screen - indicates LifeWave BST is ready for use

3. Press the green START button (left button) again. A 30-minute timer will appear and a countdown will begin.

4. After 30 minutes, the bioelectrical signal is automatically shut off, and a sound beep is heard, indicating the end of the session.

Treatment Session - Notes

- If the blue AUDIO button (middle button) is pressed on, a beep will be heard every 10 seconds during treatment, indicating that the LifeWave BST is operating properly.

- If the device identifies a problem, **e.g,** disconnection of electrodes, a beep will be heard every 2 seconds. In such an event, recheck whether all cables are connected properly and electrodes are attached to the skin.

- To disable the alarm signal at session's completion, press the blue AUDIO button (middle button) to switch it off. When the sound is disabled, you will receive only visual notification when the treatment has been completed.

- To pause a session at any time, press the red STOP button (right button) once. Press the green START button (left button) to continue the session from the point it was paused.

- To stop the session at any time, press the red STOP button (right button) twice.

End of Treatment Session

1. Once the treatment session has been completed, turn off the BST device's power switch.

2. Disconnect the electrodes' lead from the connector cable. Keep the electrodes on your skin.

3. If this is the last usage session of the pair of electrodes (the electrodes duration use is indicated on the electrode's labels), remove the electrodes by holding their edge and peeling them carefully away from the skin towards the wound. Do not pull the electrode lead to remove the electrodes.

Cleaning and Disinfecting

Clean and disinfect the BST device and cables before starting the use and at completion of treatment period.

If you have more than one wound that needs to be treated, clean and disinfect the device between sessions with separate wounds. Use the following procedure to clean and disinfect the BST device and cables:

1. Switch off the BST device using the power switch (Fig. 5).

2. Disconnect the power cable (Fig. 2) from the wall socket and from the BST device.

3. Disconnect the electrode's lead from the connector cable. (Fig. 7). Only if this is the last session of treatment with the current electrodes (the electrodes duration use is indicated on the electrode's labels), discard the electrodes with their lead.

4. Use a damp, soft, fiber-free fabric moistened with clean water to remove dirt and debris from the surface of the BST device and cables. Do not use any plastic (organic) solvents nor abrasive cleaners. Use with care in order to prevent water from entering the BST device.

5. Dry with a separate soft cloth.

6. Wipe down all surfaces of the BST device and cables with a fiber free fabric dampened with 70% alcohol, or with a commercially available disinfectant wipe.

7. Moisten another fiber-free fabric with clean water. Wipe down all surfaces and cables.

8. Dry with a separate dry fiber free fabric.

Storage and Environmental

Store LifeWave BST in a dry place at room temperature.

Environmental Allowed Conditions	
Operating temperature range	*5°C to 40°C (41°F to 104°F)*
Storage temperature range	*-10°C to 50°C (50°F to 122°F)*
Operating humidity	*5% to max. 95% RH relative humidity (non-condensing)*
Storage humidity	*30% max. 85% RH (non-condensing)*

Maintenance and Replacement Parts

If your BST device needs repair or a replacement part, please contact your physician or distributor.

Troubleshooting

The following table summarizes possible malfunctions and actions to be taken in response.

You noticed	*Possible cause*	*Actions to take*
Screen shows nothing after turning on the LifeWave BST.	1. No power to Life Wave BST 2. The contrast knob is either in the MIN or MAX position.	1. Check the power cable connections (wall socket, BST device); and\or make sure that the power switch is switched on. 2. Turn the display contrast knob and look for a change in display contrast.
Timer stopped in the middle of a session (the ✓✓ icon appears). 	The red STOP button (right button) was inadvertently pressed	Press the green START button (left button) again and note that the counter continues from the time it was stopped.
Timer stopped in the middle of a session (the ✓✗ icon appears). 	The electrical circuit between the BST device and electrodes is broken.	1. Make sure that the electrodes are firmly attached to your skin. If the problem still persists … 2. Make sure the connector cable is firmly connected to the electrode's lead and the BST device. If the problem persists … 3. Contact the physician or distributor

Technical Specifications

LifeWave BST

Physical Characteristics	
Height	130mm (5.11")
Length	256mm (10.07”)
Width	220mm (8.66")
Weight	1850 g

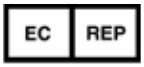
Electrical Characteristics	
Maximum output current :	6.5 mA r.m.s. (on 500 Ohm) The complete output provides net zero DC.
Power source:	120V, 60Hz, 0.2A or 230V,50Hz, 0.1A, model dependent.
Output waveform:	Symmetrical biphasic waveform composed of: 1) A rectangular pulse train - rate 4pps, pulse width 4mSec, interspaced with; 2) A stochastic (random) signal, frequency spectrum from 0 to 3000 Hz. 80% of power from 0 to 1300 Hz.

Classification	Safety
Class II Type BF	EN60601-1 IEC 60601-1:90+A1(93)+A2(95) CSA C22.2 No. 60 1.1

Electrodes

Physical Characteristics	
L x W, cm(in)	7.5cm x 4.5cm (2.96” x 1.72”)
Cable length, cm(in)	66cm (26”)

Definition of Symbols

Symbol	Description
	*Class II equipment*
	*Caution, consult accompanying documents*
	*Type BF applied equipment (according to EN/IEC 60601-1)*
	*CE Marking in accordance with the Medical Device Directive 93/42/EEC*
	*CSA mark in accordance with Canadian Standards Association - CSA/C22.2.No.601.*
	*Date of manufacture*
	*Manufacturer*
	*Serial Number*
	*Authorized representative in the European Union*
	*Waste Electrical and Electronic Equipment (WEEE) compliance symbol*
	*Do not reuse*
	*Catalog number*
	*Temperature limits*
	*Batch number*
	*Use by date*
	*Keep dry*

Warranty

LifeWave Ltd. (LifeWave), the manufacturer of the LifeWave BST, guarantees LifeWave BST Bioelectrical Signal Therapy™ ("LifeWave BST", or "device") throughout its local distribution against defects in materials and workmanship under normal use for a period of one year from the date of purchase/start of use. In case of any complaint, please contact your local distributor whose details are attached on the opposite page.

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EMC Parameters

Guidance and manufacturer's declaration for electromagnetic compatibility (EMC) for the LifeWave BST according to EN 60601-1-2:2007

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions – LifeWave BST

The **LifeWave BST** is intended for use in the electromagnetic environment specified below; the customer or the user of the **LifeWave BST** should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The **LifeWave BST** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **LifeWave BST** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity – LifeWave BST

The **LifeWave BST** is intended for use in the electromagnetic environment specified below; the customer or the user of the **LifeWave BST** should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Table 2 (Cont.)

Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable	Main power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Main power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 .	<5 %UT (>95 %dip in UT) for 0,5 cycle 40 %UT (60 %dip in UT) for 5 cycles <5 %UT 70 %UT (30 %dip in UT) for 25 cycles <5 %UT <5 %UT (>95 %dip in UT) for 5 s	<5 %UT (>95 %dip in UT) for 0,5 cycle 40 %UT (60 %dip in UT) for 5 cycles <5 %UT 70 %UT (30 %dip in UT) for 25 cycles <5 %UT <5 %UT (>95 %dip in UT) for 5 s	Main power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital environment. If the user of the **LifeWave BST** requires continued operation during power mains interruptions, it is recommended that **LifeWave BST** be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital environment.
NOTE: UT is the a.c. main voltage prior to application of the test level.			

Table 4

Guidance and manufacturer's declaration – electromagnetic immunity – LifeWave BST

The **LifeWave BST** is intended for use in the electromagnetic environment specified below; the customer or the user of the **LifeWave BST** should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the **LifeWave BST**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF	3 Vrms	3 Vrms	$d = 1.17\sqrt{P}$
			$d = 1.17\sqrt{P}$ 80 M Hz t o 800 MHz
IEC 61000-4-6	150 k Hz to 80 MHz	3 V/m	$d = 2.34\sqrt{P}$ 800 MHz t o 2,5 GHz
Radiated RF	3 V/m		where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
IEC 61000-4-3	80 MHz to 2,5 GHz		Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range [d]
			Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a - Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **LifeWave BST** is used exceeds the applicable RF compliance level above, the **LifeWave BST** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **LifeWave BST**.

b - Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 6

Recommended separation distances between

portable and mobile RF communications equipment and the LifeWave BST

The **LifeWave BST** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **LifeWave BST** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **LifeWave BST** as recommended below, according to the maximum output power of the communications equipment.

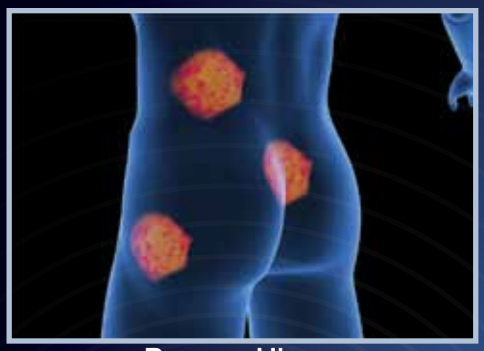
Rated maximum output power of transmitter **Watts [W]**	**Separation distance according to frequency of transmitter** **Meters [m]**		
	150kHz to 80MHz $d = 1.17\sqrt{P}$	**80MHz to 800MHz** $d = 1.17\sqrt{P}$	**800MHz to 2.5GHz** $d = 2.34\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.7	3.7	7.4
100	11.7	11.7	23.4

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

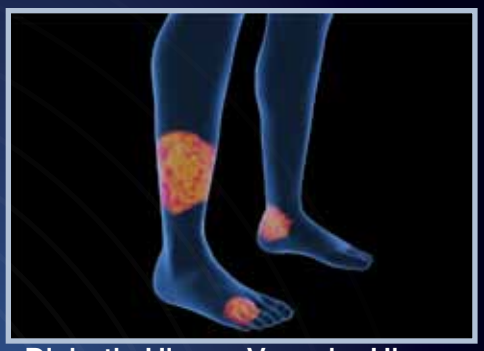
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2; These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Your Life on the Right Wave



Presure Ulcers



Diabetic Ulcers, Vascular Ulcers

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